

REMARKS

In the non-Final Office Action mailed January 22, 2008, claims 1-14, 44-64, 67 and 69 were pending. Claims 1, 5-7, 11-14, 44-47, 51-57, 61-64, 67 and 69 stand rejected, and claims 2-4, 8-10, 48-50 and 58-60 were withdrawn. Reconsideration of the present application as amended and including claims 1-14, 44-64, 67 and 69 is respectfully requested.

Regarding the withdrawal of claims 8-10, 48-50, 58 and 59, the Examiner states "in the response to the election requirement filed 12/20/2004 the Applicant's representative elected without traverse Species 1, referring to Figures 1 and 2 and never mentions Figures 3 and 4. Therefore, by doing that the Applicant's representative agrees that the election requirement to figures 1 and 2 is proper." It is respectfully submitted that the Restriction Requirement did not identify Figures 3 and 4 as a separate species, Applicant's representative could not have been reasonably expected to identify Figures 3 and 4 as a species or traverse a species election that did not exist, and that Applicant's did not have an opportunity in this application to elect Figures 3 and 4 for examination, but believed it was doing so with the election of Figures 1 and 2.

Claims 1, 5, 7, 11-14, 44, 45, 47, 51-56 and 60-69 were indicated to be rejected under 35 USC §103(a) as being unpatentable over U.S. Patent No. 5,755,797 to Baumgartner in view of U.S. Patent No. 6,620,196 to Trieu. Claim 1 recites, among other features, "wherein said plurality of reduction elements are selected in number to occupy a volume within the intravertebral space that reduces a vertebral fracture and restores the vertebral body; voids between respective ones of said plurality of reduction elements; and means for rigidly fixing said plurality of reduction elements at said volume in engagement with one another in the intravertebral space for post-operative maintenance of the reduction of the vertebral body...." (Emphasis added). Neither Baumgartner nor Trieu teach any means that functions to rigidly fix support members 7 at a volume or for post-operative maintenance of the reduction of a vertebral body.

Rather, Baumgartner teaches support members 7 that are selected in number to replace a core region of an intervertebral disk (3) and to elastically support the vertebrae on each side of the disc for movement. Furthermore, the volume occupied by support members 7 is not fixed since Baumgartner further teaches that "during loading, the support members are elastically

deformed, and the compressive forces acting in the direction of the member axis are converted into edges stresses in the annulus fibrosus.” See col. 1, line 62-65. The Office Action fails to identify any teaching or disclosure in Baumgartner that support members 7 have a fixed volume, and these structural features in claim 1 cannot be read on Baumgartner since the compression of the elastic support members 7 prevents fixing of the volume occupied by support members 7.

As admitted in the Office Action, Baumgartner does not disclose a material filling the voids of support members 7. Furthermore, even if outer shell 30 in Trieu were placed around support members 7, outer shell 30 is not taught to rigidly fix support members 7 at a volume. Rather, Trieu teaches that outer shell 30 anchors or fixes in place elastic body 15 to prevent expulsion from or excessive migration in the disc cavity. See col. 5, lines 22-27. However, teaching of fixing or anchoring the position of elastic body 15 with outer shell 30 does not teach fixing the volume of core 15 while it is prevented from expulsion of excessive migration in the disc space. Thus, there is no teaching that outer shell 30 would fix the volume of the elastic support member 7 of Baumgartner. Since at least these features in claim 1 are not taught or suggested in the cited references, a prima facie case for rejecting claim 1 has not been established.

Furthermore, one of ordinary skill in the art would be led away from claimed invention in view of Baumgartner and Trieu. Baumgartner and Trieu teach elastic support members in the spinal disc space to permit or maintain motion of the disc space in which the support members are positioned. If Baumgartner were somehow modified to include means for rigidly fixing support members 7 at a volume, then support members 7 would not elastically deform. Furthermore, the Office Action does not identify how Trieu teaches that outer shell 15 functions to rigidly fix support members 7 or elastic core 15 at a volume. The only teaching of rigidly fixing reduction elements at a volume is supplied by the Applicant’s specification, which is not a prior art reference.

Also, the invention of claim 1 includes “means for rigidly fixing said plurality of reduction elements at said volume” so that the reduction elements provide post-operative maintenance of the reduction of the vertebral body. Neither Baumgartner nor Trieu are concerned with post-operative maintenance of the reduction of the vertebral body, but rather

are directed to devices positioned in a disc space that maintain or permit spinal motion. One of ordinary skill in the art would not be led to the present invention by the combined teachings of Baumgartner and Trieu since the elastic support members taught therein would deform when subjected to spinal loading, which in turn would cause deformation of the vertebral body and circumvent the correction of the vertebral body.

Furthermore, claim 1 recites "wherein said plurality of reduction elements are selected in number to occupy a volume within the intravertebral space that reduces a vertebral fracture and restores the vertebral body...." As discussed above, Baumgartner teaches support members 7 are selected in number to occupy a spinal disc space, and not an intravertebral space. One of ordinary skill in the art would have no rational reason to select support members 7, which elastically deform under stress, in a number to occupy an intravertebral space since support members 7 would not function properly to maintain post-operative reduction of the vertebra when subjected to stress. Trieu also teaches spinal disc space implants with elastic core 15 and fails to remedy the deficiencies in Baumgartner. Therefore, claim 1 is allowable for this additional reason.

The combination of Baumgartner and Trieu also fails to teach or suggest all the elements in claims 44 and 55. Claim 44 recites "a plurality of reduction elements positionable in an intravertebral space adjacent one another in contact with bony tissue, wherein said plurality of reduction elements act randomly and radially one upon the other upon sequential positioning thereof in the intravertebral space compressing cancellous bony tissue and applying an outwardly directed corrective force in the vertebral body, wherein said plurality of reduction elements are selected in number to occupy a volume within the intravertebral space that reduces a vertebral fracture and restores the vertebral body; voids between respective ones of said plurality of reduction elements; and material filling said voids and rigidly fixing said plurality of reduction elements at said volume in engagement with one another in the intravertebral space for post-operative maintenance of the reduction of the vertebral body, said material locking said plurality of reduction elements relative to one another."

As discussed above, neither Baumgartner nor Trieu teach any material filling voids to rigidly fix support members 7 at a volume. Rather, support members 7 are selected in number

to replace a core region of an intervertebral disk (3) and to elastically support the vertebrae for movement. Furthermore, the volume occupied by support members 7 is not fixed since Baumgartner further teaches that "during loading, the support members are elastically deformed, and the compressive forces acting in the direction of the member axis are converted into edges stresses in the annulus fibrosus." See col. 1, line 62-65. The Office Action fails to identify any teaching or disclosure in Baumgartner that support members 7 have a fixed volume and these structural features in claim 1 cannot be read on Baumgartner since the compression of the elastic support members 7 prevents fixing of the volume occupied by support members 7.

Furthermore, even if outer shell 30 in Trieu were placed around support members 7, outer shell 30 is not taught to rigidly fix support members 7 at a volume. There is no teaching that outer shell 30 fixes the volume of elastic body 15, or that outer shell 30 would fix the volume of the elastic support member 7 of Baumgartner. In addition, for the same reasons discussed above with respect to claim 1, one of ordinary skill in the art would be led away from claimed invention of claim 44 in view of Baumgartner and Trieu since rigidly fixing support member 7 of Baumgartner at a volume would prevent support members 7 from elastically deforming. Also, one of ordinary skill in the art would not be led to the present invention by the combined teachings of Baumgartner and Trieu since the elastic support members taught therein would deform when subjected to spinal loading, and would not function properly to maintain post-operative reduction of the vertebra when subjected to stress.

Furthermore, Baumgartner teaches support members 7 are selected in number to occupy a volume of a spinal disc space, and not an intravertebral space. One of ordinary skill in the art would have no rational reason to select support members 7, which elastically deform under stress, in a number to occupy an intravertebral space since support members 7 would not function properly to maintain post-operative reduction of the vertebra. Trieu also teaches spinal disc space implants and fails to remedy the deficiencies in Baumgartner. Therefore, claim 44 is allowable for this additional reason.

The combination of Baumgartner and Trieu also fails to teach or suggest all the elements in claim 55. Claim 55 recites "plurality of reduction elements positionable in an

intravertebral space adjacent one another in contact with bony tissue, wherein said plurality of reduction elements include exterior surface means for facilitating engagement between adjacent reduction elements and for facilitating said reduction elements acting randomly and radially one upon the other upon sequential positioning thereof in the intravertebral space to compress cancellous bony tissue and apply an outwardly directed corrective force in the vertebral body, wherein said plurality of reduction elements are selected in number to occupy a volume within the intravertebral space that reduces a vertebral fracture and restores the vertebral body; voids between respective ones of said reduction elements; and material filling said voids and rigidly fixing said plurality of reduction elements at said volume in engagement with one another in the intravertebral space for post-operative maintenance of the reduction of the vertebral body, said material locking said plurality of reduction elements relative to one another.”

As discussed above, neither Baumgartner nor Trieu teach any material filling voids to rigidly fix support members 7 at a volume. Rather, support members 7 are selected in number to replace a core region of an intervertebral disk (3) and to elastically support the vertebrae for movement. Furthermore, the volume occupied by support members 7 is not fixed since Baumgartner further teaches that “during loading, the support members are elastically deformed, and the compressive forces acting in the direction of the member axis are converted into edges stresses in the annulus fibrosus.” *See* col. 1, line 62-65. The Office Action fails to identify any teaching or disclosure in Baumgartner that support members 7 have a fixed volume and these structural features in claim 1 cannot be read on Baumgartner since the compression of the elastic support members 7 prevents fixing of the volume occupied by support members 7.

Even if outer shell 30 in Trieu were placed around support members 7, outer shell 30 is not taught to rigidly fix support members 7 at a volume. There is no teaching that outer shell 30 fixes the volume of elastic body 15, or that outer shell 30 would fix the volume of the elastic support member 7 of Baumgartner. In addition, for the same reasons discussed above with respect to claim 1, one of ordinary skill in the art would be led away from claimed invention of claim 44 in view of Baumgartner and Trieu since rigidly fixing support member 7 of Baumgartner at a volume would prevent support members 7 from elastically deforming.

Also, one of ordinary skill in the art would not be led to the present invention by the combined teachings of Baumgartner and Trieu since the elastic support members taught therein would deform when subjected to spinal loading, which in turn would cause deformation of the vertebral body and circumvent the correction of the vertebral body.

Furthermore, Baumgartner teaches support members 7 are selected in number to occupy a volume of a spinal disc space, and not an intravertebral space. One of ordinary skill in the art would have no rational reason to select support members 7 in a number to occupy an intravertebral space since it teaches support members 7 elastically deform under stress from the spinal column loading and would not function properly to maintain post-operative reduction of the vertebra. Trieu also teaches spinal disc space implants and fails to remedy the deficiencies in Baumgartner. Therefore, claim 55 is allowable for this additional reason.

Claims 5-7, 11-14, 45-47, 51-54, 56-57, and 61-64, 67, and 69 depending from claims 1, 44 and 55 were rejected as being unpatentable over Baumgartner in view of Trieu are allowable at least since the claim from which each depends is allowable and for other reasons.

With respect to dependent claims 6, 46 and 57, the Office Action asserts it would have been an obvious matter of design choice to modify the material property of the Baumgartner reference "because Applicant has not disclosed that the PMMA material provides an advantage, is used for a particular purpose, or solves a stated problem." It is respectfully submitted that one of ordinary skill in the art would have no rational reason to modify support members 7 of Baumgartner to arrive at claims 6, 46 and 57 since Baumgartner teaches elastic support members 7 in a spinal disc space to replace the nucleus pulposus that deform under stress to replicate the spinal joint. If the elastic properties of the support members 7 were eliminated, then Baumgartner would not function properly. Therefore, withdrawal of the rejection of claims 6, 46 and 57 is respectfully requested.

Claims 67 and 69 depend from claims 1 and 44, respectively, and each recites "wherein said plurality of reduction elements are selected to occupy sufficient intravertebral space to restore a height of the vertebral body between endplates thereof." There is no indication of how these features are disclosed or taught in either Baumgartner or Trieu, and therefore a prima facie case for rejecting either of claims 67 or 69 has not been established. Furthermore, both Baumgartner and Trieu teach devices selected to occupy an intervertebral

or spinal disc space between vertebrae, but not an intravertebral space. Therefore, withdrawal of the rejection of dependent claims 67 and 69 is respectfully requested.

Reconsideration and allowance of the present application as amended and including claims 1-14, 44-64, 67, and 69 is respectfully requested. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the present application.

Respectfully submitted

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